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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
SMITH, TERRI L	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,443	WARDLE ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-95* is/are pending in the application.

4a) Of the above claim(s) *64-95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-12-04, 6-10-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1–63, drawn to an implantable device, system, and method of anchoring a device, classified in class 607, subclass 127.

II. Claims 64–66, drawn to a system for monitoring congestive heart failure, classified in class 600, subclass 301.

III. Claims 67–71, drawn to a method of monitoring congestive heart failure, classified in class 600, subclass 561.

IV. Claims 72–73, drawn to a method of monitoring congestive heart failure, classified in class 128, subclass DIG3.

V. Claims 74–87, drawn to a method of anchoring a device, classified in class 607, subclass 126.

VI. Claims 88–94, drawn to a retrieval device, classified in class 600, subclass 434.

VII. Claim 95, drawn to a method of retrieving a cardiac anchoring device, classified in class 600, subclass 466.

2. Inventions of Group I (subcombination) and Groups II and VI (combination). Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (Groups II and VI) as claimed does not require the particulars of the subcombination (Group I) as claimed because Groups II and VI do not require a distal anchor, a

helical leg or a delivery catheter. The subcombination has separate utility such as not requiring an implantable pressure sensor a retrieval device, but an implantable device for delivering shock therapy to the heart.

3. Inventions of Groups III–V and VII (process) and Group I (apparatus) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus not requiring monitoring a patient for congestive heart failure or anchoring a device in a patient's heart or retrieving a cardiac anchoring device, but rather an temporary device to provide pacing therapy to the heart. in the instant case, the combination (Groups III–IV) as claimed does not require the particulars of the subcombination (Group I) as claimed because Groups III–IV do not require a helical leg. The subcombination has separate utility such as not requiring an implantable pressure sensor or monitoring a fluid pressure, but an implantable device for delivering shock therapy to the heart.

4. Inventions of Groups III–V and VII (process) and Groups II and VI (apparatus) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process not monitoring a fluid pressure in the left atrium or expanding a pressure sensor anchor in an organ wall or positioning a tubular delivery catheter

in a wall of a patient's heart or placing a retrieval device in delivery catheter system, but rather using an external device to deliver heart therapy.

5. Inventions of Group II (combination) and Group VI (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (Group II) as claimed does not require the particulars of the subcombination (Group VI) as claimed because Group II does not require a retrieval device. The subcombination has separate utility such as not requiring an implantable pressure sensor, but a retrieval device to retrieve an anchoring device from an organ wall.

6. Inventions of Group III (subcombination) and Groups IV–V and VII (combination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (Groups IV–V and VII) as claimed does not require the particulars of the subcombination (Group III) as claimed because Groups IV–V and VII do not require monitoring a fluid pressure. The subcombination has separate utility such as not requiring expanding a pressure sensor anchor in an organ wall or positioning a tubular delivery catheter or placing a retrieval device in delivery catheter system, but delivering a pressure sensor to a hole in an atrial septum or retrieving a lead attached to a drug pump.

7. Inventions of Group IV (combination) and Groups V and VII (subcombination) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (Group IV) as claimed does not require the particulars of the subcombination (Groups V and VII) as claimed because Group IV does not require positioning a tubular delivery catheter in a wall of a patient's heart or placing a retrieval device in a delivery catheter. The subcombination has separate utility such as not requiring providing an implantable pressure sensor, but deploying an implant into a heart wall and retrieving a cardiac anchoring device from a heart wall.

8. Inventions of Group VI (apparatus) and Group IV (process) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another materially different apparatus not providing an implantable pressure sensor, but a retrieval device to remove a lead attached to a drug pump.

9. Inventions of Group VI (apparatus) and Group VII (process) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and

materially different process not placing a retrieval device in delivery catheter system, but retrieving a lead without a catheter system.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

11. During a telephone conversation with Salima Merani on Tuesday, January 17, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-63. Affirmation of this election must be made by applicant in replying to this Office Action. Claims 64 – 95 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

13. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: on page 17 in paragraph [0077], "a thickness 230" (line 5), "substantially thicker 231" (line 8), "the dimensions 232 and 234" (line 10–11), "the distance 232" (line 11), "distance 234" (line 13). Additionally, the drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "225" has been used to designate both distal radiopaque marker/marker (page 16,

paragraph [0075] and page 21, paragraph [0090]) and catheter (page 19, paragraph [0086]). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application.

The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 210B (Fig. 21). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office Action to avoid abandonment of the application.

Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1–32, 43–44, 46, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "a proximal ring" and "a distal ring" are inferentially included. It cannot be determined if these elements are being positively recited or functionally recited. To positively

claim the elements, it is suggested to first positively recite the elements. Otherwise, functional language such as "for" or "adapted to be" should be used. The Examiner has interpreted the claim as containing those elements and the claim should be amended accordingly.

Claim 43 recites the limitation "the retrieval device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 44 recites the limitation "the retrieval head" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 46 recites the limitations "the proximal ring" and "the distal ring" in lines 2–3. There is insufficient antecedent basis for these limitations in the claim.

Claim 60 recites the limitations "the proximal ring and/or the distal ring" in line 1. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1, 15, 18, 25–26, 30, 33, 39–40, 42, 46, 49, 56–57, and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Latson et al., U.S. Patent 5,861,003.

Latson discloses a proximal anchor having at least one helical leg extending between a proximal ring and a distal ring (Figs. 2 and 6); a distal anchor having at least one leg (Figs. 2 and 6); and an implant configured to be supported by the proximal and distal anchors (Fig. 2), wherein the proximal and distal anchors are configured to be movable between a collapsed

delivery position and an expanded position in which the proximal and distal anchors secure the implant to a wall of an organ within a patient/sandwich an atrial septum wall between at least one proximal anchor leg and at least one distal anchor leg and to support an implant in a septum wall (Figs. 2–3 and 6); and a delivery catheter configured to deploy an implant, a proximal anchor, and a distal anchor in a septum wall (Figs 3–6).

Latson discloses at least one proximal anchor leg passes through substantially a whole number of complete circles between a proximal ring and a distal ring of a proximal anchor (claims 15 and 46) (Figs. 2 and 6; column 6, claim 2, lines 4–5); an anchoring device is made from a biocompatible material selected from the group consisting of: nickel titanium alloys, stainless steel, ELGILOY, and MP35N (claims 18 and 49) (column 4, lines 50–51); at least one member of the group consisting of a proximal anchor, a distal anchor and an implant comprises one or more radiopaque markers configured to facilitate visualization under fluoroscopy (claims 25 and 56) and a proximal ring and/or a distal ring of a proximal anchor comprise a radiopaque marker (claims 30 and 60) (Figs. 2 and 6; column 4, lines 42–43); a portion of an element comprising one or more radiopaque markers is coated with a polymeric material adapted to prevent galvanic corrosion (claims 26 and 57) (column 4, lines 37–38).

Latson discloses a retrieval device configured to grasp a proximal ring of a proximal anchor in a relaxed state (Fig. 5), and to retract a proximal ring of a proximal anchor proximally relative to a distal ring, thereby returning a proximal anchor to a compressed state (claim 40) (Fig. 4).

18. Claims 33, 48, 56, and 58–59, are rejected under 35 U.S.C. 102(b) as being anticipated by Ruiz, U.S. Patent 5,976,174.

Ruiz discloses an implant configured to be implanted within a patient (Fig. 1A); a proximal anchor comprising at least one helical leg configured to expand from a compressed state to a relaxed state (Figs. 2 and 1A); a distal anchor comprising at least one leg configured to expand from a compressed state to an expanded state (Figs. 2 and 1A); wherein a proximal anchor and a distal anchor are configured to sandwich an atrial septum wall between at least one proximal anchor leg and at least one distal anchor leg and to support an implant in a septum wall (Fig. 1B); and a delivery catheter configured to deploy an implant, a proximal anchor, and a distal anchor in a septum wall (Fig. 2).

Ruiz discloses proximal anchor leg and the distal anchor leg are configured to secure the implant to organ walls with varying thicknesses (column 3, lines 49–52); at least one member of the group consisting of a proximal anchor, a distal anchor and an implant comprises one or more radiopaque markers configured to facilitate visualization under fluoroscopy and a radiopaque marker is placed in one or more low flex zones and at least one distal anchor leg comprises the radiopaque marker (column 4, lines 13–15)

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 2–13, 19–22, 24, 31, 34–38, 44, 50–53, 55and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latson et al. as applied to claims 1 and 33 above, and in view of Schwartz, U.S. PG-PUB 2002/0077555.

Latson et al. does not disclose an implant is a diagnostic tool (claims 2 and 34); an implant is a therapeutic tool (claims 3 and 36); a diagnostic tool comprises apparatus operable to measure one or more physiological parameters/parameters selected from the group consisting of: pressure, oxygen and electrical activity (claims 4–7, and 35); an implant is selected from the group consisting of one or more of the following: stimulating electrodes, ultrasound transducers, drug delivery systems, pacing leads, and electrocardiogram leads (claim 10); an implant is a sensor (claims 11 and 61); a sensor is a sensing electrode, oxygen partial pressure sensor or an oxygen saturation sensor (claim 12); a pressure sensor (claim 13); a sensor comprises a pressure sensing face configured to measure a fluid pressure in a left atrium of a patient's heart (claims 19 and 50); proximal and distal anchors are configured to support the sensor such that the pressure sensing face is substantially coplanar with a distal side of an atrial septum wall (claims 20 and 51); a proximal and distal anchors are configured to support a sensor such that a pressure sensing face is spaced distally and proximally from a plane of a distal side of an atrial septum wall (claims 21 and 22); a sensor is configured to attach to an electrical lead (claims 24 and 55); a sensor comprises/an implant comprises a pressure sensor having a cylindrical body with at least

one annular groove configured to engage a portion of the proximal anchor or a portion of the distal anchor in order to retain the proximal or distal anchor against axial movement relative to the sensor (claims 31 and 62); a retrieval head comprises an internal diameter configured to allow the retrieval head to pass over a sensor lead (claim 44).

However, Schwartz discloses an implant is a diagnostic tool (claims 2 and 34) (paragraph [0010], lines 2–3); an implant is a therapeutic tool (claims 3 and 36) (paragraph [0006]); a diagnostic tool comprises apparatus operable to measure one or more physiological parameters/parameters selected from the group consisting of: pressure, oxygen and electrical activity (claims 4–7, and 35) (paragraph [0022], lines 2–3; paragraph [0003], lines 5–6; Figs. 5–9, respectively); an implant is selected from the group consisting of one or more of the following: stimulating electrodes, ultrasound transducers, drug delivery systems, pacing leads, and electrocardiogram leads (claim 10) (paragraph [0003], lines 18–24); an implant is a sensor (claims 11 and 61) (element 50); a sensor is a sensing electrode, oxygen partial pressure sensor or an oxygen saturation sensor (claim 12) (paragraph [0003], lines 5–6); a pressure sensor (claim 13) (paragraph [0006], line 5); a sensor comprises a pressure sensing face configured to measure a fluid pressure in a left atrium of a patient's heart (claims 19 and 50) (paragraphs [0114]–[0115]); proximal and distal anchors are configured to support a sensor such that a pressure sensing face is substantially coplanar with a distal side of an atrial septum wall (claims 20 and 51) (Fig. 11); a proximal and distal anchors are configured to support a sensor such that a pressure sensing face is spaced distally and proximally from a plane of a distal side of an atrial septum wall (claims 21 and 22) (Fig. 11); a sensor is configured to attach to an electrical lead (claims 24 and 55) (paragraph [0003], lines 18–21); a sensor comprises/an implant comprises a

pressure sensor having a cylindrical body with at least one annular groove configured to engage a portion of the proximal anchor or a portion of the distal anchor in order to retain the proximal or distal anchor against axial movement relative to the sensor (claims 31 and 62) (Figs. 3–5); a retrieval head comprises an internal diameter configured to allow a retrieval head to pass over a sensor lead (claim 44) (Fig. 16A; paragraph [0004], line 2) to provide a system capable of various medical applications using an implantable device that is capable of being several different devices and systems, as well as performing several different therapies; and optimally implanting and anchoring the device or system to perform in the most effective and efficient manner possible.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Latson et al. to include all the limitations set forth above in the listed claims (NOTE: For the sake of brevity, Examiner will not list the claims again), as taught by Schwartz to provide a system capable of various medical applications using an implantable device that is capable of being several different devices and systems, as well as performing several different therapies; and optimally implanting and anchoring the device or system to perform in the most effective and efficient manner possible.

Latson et al. does not disclose a therapeutic tool comprises apparatus operable to deliver one or more pharmaceutical agents and one or more electrical signals to a patient (claims 8, 9, 37, and 38). However, Schwartz discloses a therapeutic tool (paragraph [0006]) but does not disclose expressly a therapeutic tool comprises apparatus operable to deliver one or more pharmaceutical agents and one or more electrical signals to a patient. Accordingly, it is well known in the art to use a therapeutic tool as taught by Schwartz because therapy provided by a

therapeutic tool sustains and maintains a patient's well being. Consequently, it would have been an obvious matter of engineering design choice to a person of ordinary skill in the art at the time the invention was made to modify the therapeutic tool, as taught by Schwartz in the modified inventions of Latson et al. and Schwartz, to deliver one or more pharmaceutical agents and one or more electrical signals to a patient.

22. Claims 14, 23, 32, 45, 54 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latson et al. as applied to claims 1 and 33 above, and in view of Huebsch et al., U.S. Patent 6,024,756.

Latson et al. does not disclose a proximal anchor comprises at least three legs (claims 14 and 45) and a proximal anchor, a distal anchor and an implant comprise interlocking structures configured to rigidly secure a proximal anchor, a distal anchor and an implant to one another (claims 23 and 54) and a distal anchor comprises a plurality of legs comprising slots configured to promote tissue overgrowth (claims 32 and 63). However, Huebsch discloses a proximal anchor comprises at least three legs (claims 14 and 45) (Fig. 3) to provide increased support arm strength (column 8, lines 18–19) and a proximal anchor, a distal anchor and an implant comprise interlocking structures configured to rigidly secure a proximal anchor, a distal anchor and an implant to one another (claims 23 and 54) (Figs. 6, 9, and 16) to prevent the device from opening up to resume its original shape and a distal anchor comprises a plurality of legs comprising slots configured to promote tissue overgrowth (claims 32 and 63) (Fig. 3) to help in the stabilization of the device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Latson et al. to include a proximal anchor comprises at least three legs (claims 14 and 45) and a proximal anchor, a distal anchor and an implant comprise interlocking structures configured to rigidly secure a proximal anchor, a distal anchor and an implant to one another (claims 23 and 54) and a distal anchor comprises a plurality of legs comprising slots configured to promote tissue overgrowth (claims 32 and 63), as taught by Huebsch to provide increased support arm strength and to prevent the device from opening up to resume its original shape and to help in the stabilization of the device.

23. Claims 16–17, 27–29, 41and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latson et al. as applied to claims 16 and 25 above, and in view of Ruiz, U.S. Patent 5,976,174.

Latson et al. does not disclose at least one proximal anchor leg and at least one distal anchor leg are configured to secure an implant to organ walls with varying thicknesses (claim 17). However, Ruiz discloses at least one proximal anchor leg and at least one distal anchor leg are configured to secure an implant to organ walls with varying thicknesses (column 3, lines 49–52) to allow the device to remain in contact with the organ wall so that the device will maintain optimal performance.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Latson et al. to include at least one proximal anchor leg and at least one distal anchor leg are configured to secure an implant to organ walls with varying thicknesses, as taught by Ruiz to allow the device to remain in contact with the organ wall so that the device will maintain optimal performance.

Regarding claims 16 and 47, Latson et al. does not disclose at least one proximal anchor leg has a lower spring force than at least one distal anchor leg. However, Ruiz discloses the claimed invention except for a lower spring force in a proximal anchor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a lower spring force in a proximal anchor, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re* Boesch, 617 F.2d 272, 205 USPQ (CCPA 1980). See MPEP 2144.05

Latson et al. does not disclose one or more radiopaque markers are placed in low flex zones (claim 27) and tips of at least one distal anchor leg comprise one or more radiopaque markers (claim 28). However, Ruiz discloses one or more radiopaque markers are placed in low flex zones and tips of at least one distal anchor leg comprise one or more radiopaque markers (column 4, lines 13–15) to allow visibility under a fluoroscope for aiding in accuracy of implantation of the device; a retrieval device comprises a distal ring with at least one distally-extending grasping hook, a proximal ring, and at least one helical leg extending between the proximal ring and the distal ring (claim 42) and a push/pull ribbon (release mechanism) (claim 43) (Fig. 4) to aid in the ease of extraction of the device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Latson et al. to include one or more radiopaque markers are placed in low flex zones (claim 27) and tips of at least one distal anchor leg comprise one or more radiopaque markers (claim 28), as taught by Ruiz to allow visibility under a fluoroscope for aiding in accuracy of implantation of the device and to aid in the ease of extraction of the device.

With respect to claim 29, Larson discloses a proximal ring of a proximal anchor, but he does not expressly disclose that the proximal ring of the proximal anchor comprises one or more radiopaque markers. However, Larson does disclose that the distal ring of the proximal anchor comprises one or more radiopaque markers (Figs. 2 and 6; column 4, lines 42–43). Accordingly, it is well known in the art to include radiopaque markers on components of an anchor in order to facilitate in fluoroscopic visualization of the device during implant or extraction. Consequently, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Latson et al. to include a proximal ring of a proximal anchor comprises one or more radiopaque markers in order to facilitate in fluoroscopic visualization of the device during implant or extraction.

Regarding claim 41, Larson et al. discloses the claimed invention except for a plurality of distally-extending grasping hooks. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a plurality of distally-extending grasping hooks, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
January 23, 2006
23 January 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
1/23/6